



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,671	11/09/2005	Hideaki Yamaoka	TOYA114.007APC	1379

20995 7590 11/01/2007
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

LONG, SCOTT

ART UNIT	PAPER NUMBER
----------	--------------

1633

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

11/01/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcarter@kmob.com
eOAPilot@kmob.com

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p align="center">10/550,671</p>	<p>Applicant(s)</p> <p align="center">YAMAOKA ET AL.</p>	
	<p>Examiner</p> <p align="center">Scott D. Long</p>	<p>Art Unit</p> <p align="center">1633</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|--|---|

DETAILED ACTION

The examiner acknowledges receipt of Applicant's Remarks and claim amendments, filed 28 August 2007.

Claim Status

Claims 1-6 and 8-9 are pending. Claims 1 and 8 are amended. Claim 7 is canceled. Claims 1-6 and 8-9 are under current examination.

Priority

This application claims benefit as a 371 of PCT/JP04/04074 (filed 03/24/2004). This application claims benefit from foreign application JAPAN 2003-082739 (filed 03/25/2003). The examiner was in error in his previous action in asserting that the application was not entitled to a benefit date, based on the foreign application, JAPAN 2003-082739. The examiner has reassessed the claim to benefit. Accordingly, the instant application has been granted the benefit date, 25 March 2003, from JAPAN 2003-082739.

Response to Arguments - Claim Rejections 35 USC § 112

Response to Arguments – 35 USC 112, second paragraph

Applicant's arguments, see pages 3-4 and Claim amendments, filed 28 August 2007, with respect to claims 1 and 3 have been fully considered and are persuasive.

The rejection of Claim 1 under 35 USC 112, second paragraph, have been made moot by the claim amendments (regarding "ccm") submitted on 28 August 2007 and is hereby withdrawn.

The rejections of Claims 1 and 3 under 35 USC 112, second paragraph, have been overcome by applicant's arguments (regarding "the subunits") submitted on 28 August 2007 and is hereby withdrawn.

However, the examiner is not completely convinced by the applicant's argument that "an expressible form" of the α -subunit and β -subunit of glucose dehydrogenase is limited to the meaning that the subunit genes are linked to a promoter and are expressed in bacterium. Nevertheless, the examiner is withdrawing the rejection, because the applicant has put this interpretation on the record and the examiner does not feel this is an impediment to further examination. Therefore, the rejection of Claim 1 under 35 USC 112, second paragraph, has been overcome by applicant's arguments and is hereby withdrawn.

Response to Arguments - Claim Rejections 35 USC § 102

Applicant's arguments (Remarks, page 4) filed on 28 August 2007 have been fully considered and they are persuasive.

The examiner persuasively argues that Sode does not teach all the limitations of the newly amended claims. The examiner agrees with this argument.

Therefore, the examiner hereby withdraws the rejection of claims 1-6 under 35 U.S.C. 102(b) as anticipated by Sode (WO/2002/36779, published 10 May 2002).

Response to Arguments - Claim Rejections 35 USC § 103

Applicant's arguments filed 24 28 August 2007 have been fully considered but they are not persuasive.

The applicant traverses the rejection of claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sode (WO/2002/36779, published 10 May 2002) in view of Herbaud et al. (Biochim. Biophys Acta. 2000; Vol.1481(1): 18-24) as evidenced by Arslan et al. (Biochem. Biophys. Res. Commun. 251 (1998) 744-747). The applicant offers three arguments in response to the rejection: (1) "the β -subunit of GDH is not taught by any of the cited references" (Remarks, page 4); (2) there is no apparent reason to combine; and (3) it is "not predictable that an enzyme complex having the α -subunit and the β -subunit would be produced recombinantly and have enzyme activity" (Remarks, page 5). Additionally, the applicant argues that the claimed invention produced GDH activity in *Escherichia* bacterium which was unexpectedly high when compared to wild type strain.

Contrary to the applicant's assertions, the art does teach the β -subunit of GDH, and provides sufficient reasons to combine the references. The applicant asserts that "Sode discloses the partial 5' terminal sequence of the nucleotide sequence encoding β -subunit of GDH and the N-terminal amino acid sequence thereof, Sode does not disclose the complete sequence of the β -subunit" (Remarks, page 4). However, Sode teaches, "the inventors of the present invention have further advanced the study on GDH of *Burkholderia cepacia* KS1 strain and were successful in isolating a DNA

Art Unit: 1633

encoding a GDH β subunit" (parag.0011). The examiner suggests that in light of the recent KSR decision, this necessity for a "reason or suggestion" is no longer required. KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396). Regarding the rationale for combining prior art elements according to known methods to yield predictable results, all of the claimed elements were known in the prior art and one skilled in the art could have combined the element as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Each of the elements (α - and β -subunit of GDH; ccm Operon; and) are taught by Sode in view of Herbaud et al. and as evidenced by Arslan et al. It would be therefore predictably obvious to use a combination of these three elements in a recombinant *Escherichia* bacterium. Regarding the applicant's assertion that the claimed invention provides unexpectedly levels of GDH, the teachings of the references cited in the 35 USC 103 rejection also suggest unexpectedly levels of GDH. For example, Herbaud et al. teach *E. coli* transformed with "pEC86 that contains the ccm genes" (page 19, col.2), in particular, those encoding α -subunit, β -subunit, and γ -subunit. Herbaud also teach "when the ccm genes are provided on a plasmid together with the structural gene for a mono- and a diheme c-type cytochrome, the cytochrome maturation occurs and seems to be increased" (page 18, col.2). Therefore, the

Art Unit: 1633

examiner hereby maintains the rejection of claims 1-6 and 8-9 under 35 USC 103(a) as obvious over Sode in view of Herbaud et al. and as evidenced by Arslan et al.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
Patent Examiner
Art Unit 1633

/Janet L. Epps-Ford/
Primary Examiner
Art Unit 1633

JLE